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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,426	03/09/2001	Bruce Mortensen	0300-0016	4832

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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 12/19/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,426

Applicant(s)

MORTENSEN ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-28,30-32,34-37 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28,30-32,34-37 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/02 has been entered.

2. Applicant's amendment filed 9/25/02 in Paper No. 16 is acknowledged and entered. Claim 29 is canceled. Claims 26-28 are amended. Claims 45-47 are added. Claims 26-28, 30-32, 34-37, and 45-47 are pending.

3. The following rejections are necessitated by the amendments.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 26-28, 30-31, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US Patent 6,040,194) in view of Bernard et al (*Analytical Biochem*, 255:101-107, 1998).

Chick et al. disclose using FRET (fluorescence resonance energy transfer) for analytes detection (col. 3, lines 9-24). The reagent (composition) includes two components, one of which is labeled with an energy-absorbing donor molecule and the other is labeled with an energy-absorbing acceptor molecule. The fluorescence associated with the resonance energy transfer from donor and acceptor (FRET) is measured (col. 3, lines 15-19). The components could be members of a specific binding pair or ligands that bind specifically to different portions of the analyte (col. 3, lines 19-24). The donor and acceptor pair can be fluorophores (col. 7, lines 37-67 to col. 8, lines 1-3). The fluorophore can be covalently attached to the components ((col. 10, lines 19-41). The analytes include enzymes, antibodies, antigens, polynucleotides (col. 5, lines 15-32 and 52-56) or combination of antibody-antigen, receptor-ligand, and enzyme-substrate (col. 9, lines 43-50) (referring to claim 30-32 and 46). In the embodiment where two ligands that binds to different portions (sites) of the analyte molecule, the ligands could be antibodies and are labeled with the fluorophores (col. 10, lines 18-35) (referring to an indirect attachment).

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Chick et al. do not expressly disclose that the donor-acceptor pair is fluorescein and cyanine 5.

Bernard et al. discloses binding pair, which is a complementary oligonucleotide (pg. 101, right col. 2nd paragraph; pg. 102, left col., lines 1-2 and 4-8). A member of the binding pair is directly attached to fluorescein (a complementary fluorescein probe) and the other member of the binding pair is directly attached to cyanine 5 (a Cy5-labeled PCR strand) (pg. 102, left col., lines 4-8). The binding pair is associated so that the fluorescein and cyanine 5 are in fluorescence resonance energy transfer to each other (pg. 102, left col., lines 30-44).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include fluorescein and cyanine as the donor-acceptor pair in FRET as taught by Bernard et al. for the donor-acceptor pair in the composition of analytes detection using FRET of Chick et al. One of ordinary skill in the art would have been motivated to include fluorescein and cyanine as the donor-acceptor pair in FRET in the composition of analytes detection using FRET of Chick et al. because Chick et al. disclose that any combination of donor-acceptor pair can be use in FRET (col. 7, lines 37-41). Bernard et al. teaches that the combination of fluorescein and cyanine can be use as a donor-acceptor pair in FRET (pg. 102, left col., lines 30-44). Therefore, the choice of donor-acceptor pair for FRET would depend on the availability of fluorophores.

1. Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US Patent 6,040,194) in view of Bernard et al (*Analytical Biochem*, 255:101-107, 1998) as

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applied to claims 26-28, 30-31, and 45-47 above, and further in view of Dykens et al. (US Patent 6,280,981 B1).

The composition using FRET (fluorescence resonance energy transfer) for analytes detection of Bernard and Chick applied for the reasons discussed above.

Both Bernard and Chick do not expressly disclose the proximity of the fluorescence resonance energy transfer.

Dykens teaches that the efficiency of the resonance energy transfer is dictated largely by the proximity of the donor and acceptor (col. 15, line 38-52) and that those familiar with the art will readily appreciate that donor-acceptor intermolecular distance is a cardinal determinative factor for the efficiency of the resonance energy transfer (col. 31, line 14-17). Dykens et al list the proximity distance in col. 31, line 1-9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the proximity of the fluorescence resonance energy transfer as taught by Dykens in the composition of analytes detection using FRET of Chick et al. as modify by Bernard et al. One of ordinary skill in the art would have been motivated to include the proximity of the fluorescence resonance energy transfer in the composition of analytes detection using FRET of Chick et al. as modify by Bernard et al. for the advantage of providing a more efficient determination the resonance energy transfer in different combination of binding pair. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
December 13, 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER